HERMETIC PACKAGES AND FEEDTHROUGHS FOR NEURAL PROSTHESES

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SUMMARY

During the past quarter we continued testing of glass packages under accelerated conditions, continued the characterization of the receiver circuitry for the single-channel microstimulator and assembled a few microstimulators using the old circuit chips, and completed the design and simulation of a fully integrated multichannel nerve stimulation system.

Our most significant package testing results to date are those obtained from a series of silicon-glass packages that have been soaking in DI water at 85°C and 95°C for more than a year. We reported in the last progress reports that all packages soaking at 95°C had failed. There were also 4 packages that were soaking at 85°C. All these four packages are still dry and under test. Of the original 10 packages, the longest going sample has reached a maximum of 1047 days at 85°C and 484 days at 95°C. If we assume that all of the packages at 85°C failed the same time that the 95°C packages failed, we can calculate a worst case mean time to failure of 258 days for the samples at 85°C, and of 119 days for the samples soaking at 95°C. The worst case MTTF at body temperature based on these tests is then calculated to be 59 years. These tests have been very encouraging and clearly indicate the packages can last for many years in water. In addition to these tests in DI water, we had also soaked several packages in ***saline*** at the above two temperatures. The results obtained from these tests were reported in the last progress report. We also have had 4 packages soaking at room temperature in saline. The longest lasting package has been soaking for 939 days, and an average soak period of 776 days at room temperature. We will continue to observe these packages for any sign of leakage.

In addition, a new set of tests were initiated this past quarter in saline. Five devices are now soaking at 85° and 95°C each and we will monitor these devices for signs of leakage or dissolution. The dissolution rate of polysilicon was measured in saline at 85°C (0.6μm/day), and 95°C (1.6μm/day). These measurements clearly indicate the difficulty of testing these materials at elevated temperatures. Silicone-coated samples are used to alleviate some of these problems.

During the past quarter our efforts in the testing, characterization, and assembly of single-channel microstimulators were interrupted because of the departure of one of the students (Mr. Anthony Coghlan) in our group, who decided not to pursue his doctoral research. Since we could not determine the source of the problem, we have assumed that this leakage is caused by some problem in processing the wafers. Therefore, our plans are to refabricate these circuits at the same time when we are fabricating the multi-channel microstimulators for nerve regeneration applications.

Finally, during the past quarter we completed the design and layout of the circuitry for a fully integrated 8-channel mini-microstimulator that can operate using on-chip coils. This circuitry can be used for peripheral nerve stimulation applications and can deliver current pulses to any of 8 electrodes. The circuitry has been layed out and will go out for masks within the next two weeks. We plan starting the fabrication as soon as masks come back, and we believe that fabrication will be complete by the end of the next quarter. We also further characterized on-chip coils for power and data reception and are confident that sufficient levels of power can be transmitted to these on-chip coils for peripheral nerve applications. The mini-microstimulator can thus operate without the need for any hybrid components, which will make the fabrication and assembly of these systems much easier.

1. INTRODUCTION

This project deals with the development of hermetic, biocompatible micropackages and feedthroughs for use in a variety of implantable neural prostheses for sensory and motor handicapped individuals. The project also aims at continuing work on the development of a telemetrically powered and controlled neuromuscular microstimulator for functional electrical stimulation. The primary objectives of the project are: 1) the development and characterization of hermetic packages for miniature, silicon-based, implantable three-dimensional structures designed to interface with the nervous system for periods of up to 40 years; 2) the development of techniques for providing multiple sealed feedthroughs for the hermetic package; 3) the development of custom-designed packages and systems used in chronic stimulation or recording in the central or peripheral nervous systems in collaboration and cooperation with groups actively involved in developing such systems; and 4) establishing the functionality and biocompatibility of these custom-designed packages in *in-vivo* applications. Although the project is focused on the development of the packages and feedthroughs, it also aims at the development of inductively powered systems that can be used in many implantable recording/stimulation devices in general, and of multichannel microstimulators for functional neuromuscular stimulation in particular.

Our group here at the Center for Integrated Sensors and Circuits at the University of Michigan has been involved in the development of silicon-based multichannel recording and stimulating microprobes for use in the central and peripheral nervous systems. More specifically, during the past two contract periods dealing with the development of a single-channel inductively powered microstimulator, our research and development program has made considerable progress in a number of areas related to the above goals. A hermetic packaging technique based on electrostatic bonding of a custom-made glass capsule and a supporting silicon substrate has been developed and has been shown to be hermetic for a period of at least a few years in salt water environments. This technique allows the transfer of multiple interconnect leads between electronic circuitry and hybrid components located in the sealed interior of the capsule and electrodes located outside of the capsule. The glass capsule can be fabricated using a variety of materials and can be made to have arbitrary dimensions as small as 1.8mm in diameter. A multiple sealed feedthrough technology has been developed that allows the transfer of electrical signals through polysilicon conductor lines located on a silicon support substrate. Many feedthroughs can be fabricated in a small area. The packaging and feedthrough techniques utilize biocompatible materials and can be integrated with a variety of micromachined silicon structures.

The general requirements of the hermetic packages and feedthroughs to be developed under this project are summarized in Table 1. Under this project we will concentrate our efforts to satisfy these requirements and to achieve the goals outlined above. There are a variety of neural prostheses used in different applications, each having different requirements for the package, the feedthroughs, and the particular system application. The overall goal of the program is to develop a miniature hermetic package that can seal a variety of electronic components such as capacitors and coils, and integrated circuits and sensors (in particular electrodes) used in neural prostheses. Although the applications are different, it is possible to identify a number of common requirements in all of these applications in addition to those requirements listed in Table 1. The packaging and feedthrough technology should be capable of:

1- protecting non-planar electronic components such as capacitors and coils, which typically have large dimensions of about a few millimeters, without damaging them;
2- protecting circuit chips that are either integrated monolithically or attached in a hybrid fashion with the substrate that supports the sensors used in the implant;
3- interfacing with structures that contain either thin-film silicon microelectrodes or conventional microelectrodes that are attached to the structure;

Table 1: General Requirements for Miniature Hermetic Packages and Feedthroughs for Neural Prostheses Applications

Package Lifetime:
$\geq$ 40 Years in Biological Environments @ 37°C

Packaging Temperature:
$\leq$360°C

Package Volume:
10-100 cubic millimeters

Package Material:
Biocompatible
Transparent to Light
Transparent to RF Signals

Package Technology:
Batch Manufactureable

Package Testability:
Capable of Remote Monitoring
In-Situ Sensors (Humidity & Others)

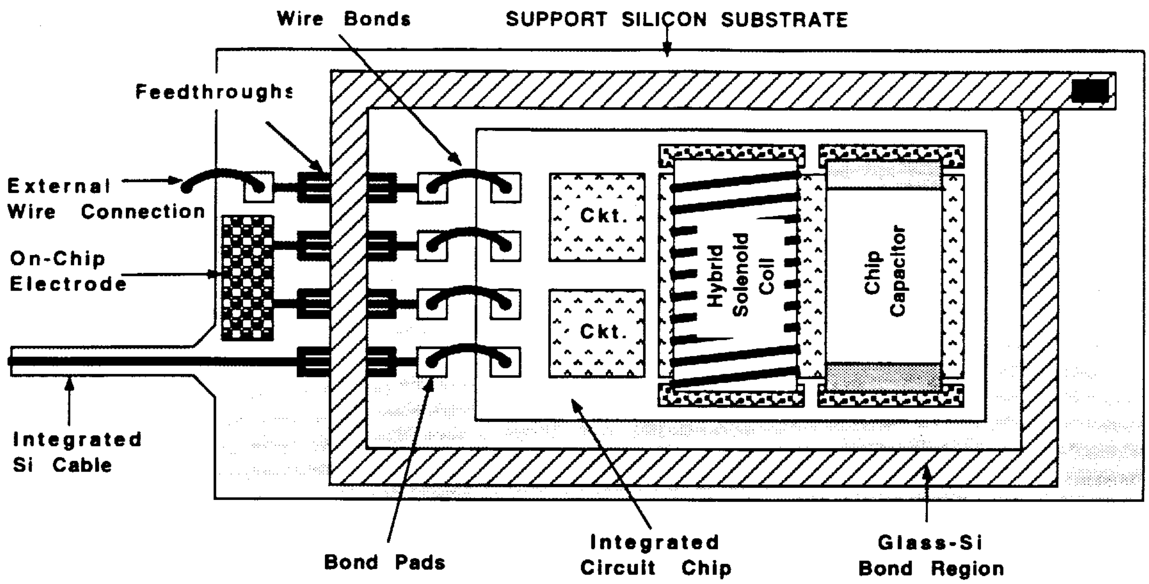
Feedthroughs:
At Least 12 with $\leq$125μm Pitch
Compatible with Integrated or Hybrid Microelectrodes
Sealed Against Leakage

Testing Protocols:
In-Vitro Under Accelerated Conditions
In-Vivo in Chronic Recording/Stimulation Applications

We have identified two general categories of packages that need to be developed for implantable neural prostheses. The first deals with those systems that contain large components like capacitors, coils, and perhaps hybrid integrated circuit chips. The second deals with those systems that contain only integrated circuit chips that are either integrated in the substrate or are attached in a hybrid fashion to the system.

Figure 1 shows our general proposed approach for the package required in the first category. This figure shows top and cross-sectional views of our proposed approach here. The package is a glass capsule that is electrostatically sealed to a support silicon substrate. Inside the glass capsule are housed all of the necessary components for the system. The electronic circuitry needed for any analog or digital circuit functions is either fabricated on a separate circuit chip that is hybrid mounted on the silicon substrate and electrically connected to the silicon substrate, or integrated monolithically in the support silicon substrate itself. The attachment of the hybrid IC chip to the silicon substrate can be performed using a number of different technologies such as simple wire bonding between pads located on each substrate, or using more sophisticated techniques such as flip-chip solder reflow or tab bonding. The larger capacitor or microcoil components are mounted on either the substrate or the IC chip using appropriate epoxies or solders. This completes the assembly of the electronic components of the system and it should be possible to test the system electronically at this point before the package is completed. After testing, the system is packaged by placing the glass capsule over the entire system and bonding it to the silicon substrate using an electrostatic sealing process. The cavity inside the glass package is now hermetically sealed against the outside environment. Feedthroughs to the outside world are provided using the grid-feedthrough technique discussed in previous reports. These feedthroughs transfer the electrical signals between the electronics inside the package and various elements outside of the package. If the package has to interface with conventional microelectrodes, these microelectrodes can be attached to bonding pads located outside of the package; the bond junctions will have to be protected from the external environment using various polymeric encapsulants. If the package has to interface with on-chip electrodes, it can do so by integrating the electrode on the silicon support substrate. Interconnection is simply achieved using on-chip polysilicon conductors that make the feedthroughs themselves. If the package has to interface with remotely located recording or stimulating electrodes that are attached to the package using a silicon ribbon cable, it can do so by integrating the cable and the electrodes again with the silicon support substrate that houses the package and the electronic components within it.

Figure 2 shows our proposed approach to package development for the second category of applications. In these applications, there are no large components such as capacitors and coils. The only component that needs to be hermetically protected is the electronic circuitry. This circuitry is either monolithically fabricated in the silicon substrate that supports the electrodes (similar to the active multichannel probes being developed by the Michigan group), or is hybrid attached to the silicon substrate that supports the electrodes (like the passive probes being developed by the Michigan group). In both of these cases the package is again another glass capsule that is electrostatically sealed to the silicon substrate. Notice that in this case, the glass package need not be a high profile capsule, but rather it need only have a cavity that is deep enough to allow for the silicon chip to reside within it. Note that although the silicon IC chip is originally 500µm thick, it can be thinned down to about 100µm, or can be recessed in a cavity created in the silicon substrate itself. In either case, the recess in the glass is less than 100µm deep (as opposed to several millimeters for the glass capsule). Such a glass package can be easily fabricated in a batch process from a larger glass wafer.



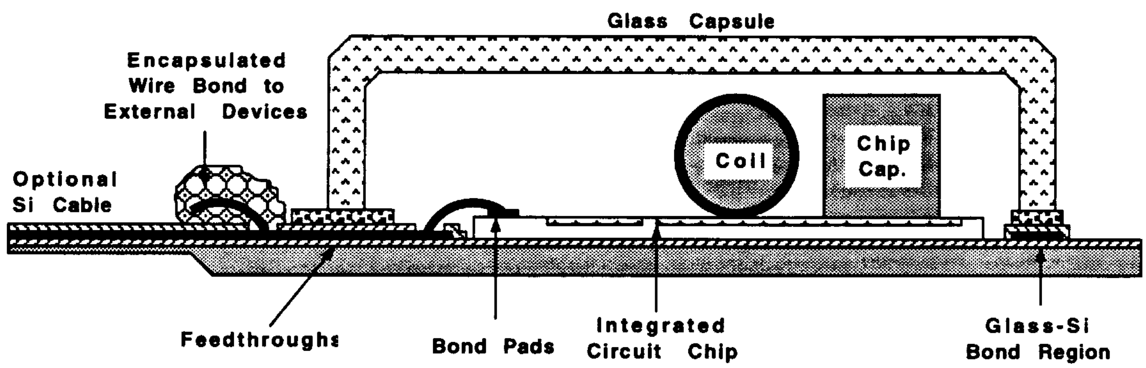


Figure 1: A generic approach for packaging implantable neural prostheses that contain a variety of components such as chip capacitors, microcoils, and integrated circuit chips. This packaging approach allows for connecting to a variety of electrodes.

We believe the above two approaches address the needs for most implantable neural prostheses. Note that both of these techniques utilize a silicon substrate as the supporting base, and are not directly applicable to structures that use other materials such as ceramics or metals. Although this may seem a limitation at first, we believe that the use of silicon is, in fact, an advantage because it provides several benefits. First, it is biocompatible and has been used extensively in biological applications. Second, there is a great deal of effort in the IC industry in the development of multi-chip modules (MCMs), and many of these efforts use silicon supports because of the ability to form high density interconnections on silicon using standard IC fabrication techniques. Third, many present and future implantable probes are based on silicon micromachining technology; the use of our proposed packaging technology is inherently compatible with most of these probes, which simplifies the overall structure and reduces its size.

Once the above packages are developed, we will test them in biological environments by designing packages for specific applications. One of these applications is in recording neural activity from cortex using silicon microprobes developed by the Michigan group under separate contracts. The other involves the chronic stimulation of muscular tissue using a multichannel microstimulator for the stimulation of the paralyzed larynx. This application has been developed at Vanderbilt University. Once the device is built, it will be used by our colleagues at Vanderbilt to perform both biocompatibility tests and functional tests to determine package integrity and suitability and device functionality for the reanimation of the paralyzed larynx. The details of this application will be discussed in future progress reports.

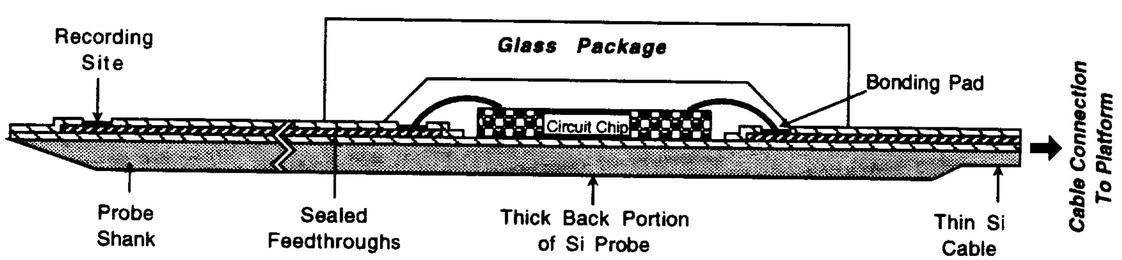


Figure 2: Proposed packaging approach for implantable neural prostheses that contain electronic circuitry, either monolithically fabricated in the probe substrate or hybrid attached to the silicon substrate containing microelectrodes.

2. ACTIVITIES DURING THE PAST QUARTER

2.1 Hermetic Packaging

Over the past few years we have developed a bio-compatible hermetic package with high density multiple feedthroughs. This technology utilizes electrostatic bonding of a custom-made glass capsule to a silicon substrate to form a hermetically sealed cavity, as shown in Figure 3. Feedthrough lines are obtained by forming closely spaced polysilicon lines and planarizing them with LTO and PSG. The PSG is reflowed at 1100°C for 2 hours to form a planarized surface. A passivation layer of oxide/nitride/oxide is then deposited on top to prevent direct exposure of PSG to moisture. A layer of fine-grain polysilicon (surface roughness 50Å rms) is deposited and doped to act as the bonding surface. Finally, a glass capsule is bonded to this top polysilicon layer by applying a voltage of 2000V between the two for 10 minutes at 320 to 340°C, a temperature compatible with most hybrid components. The glass capsule can be either custom molded from Corning code #7740 glass, or can be batch fabricated using ultrasonic micromachining of #7740 glass wafers.

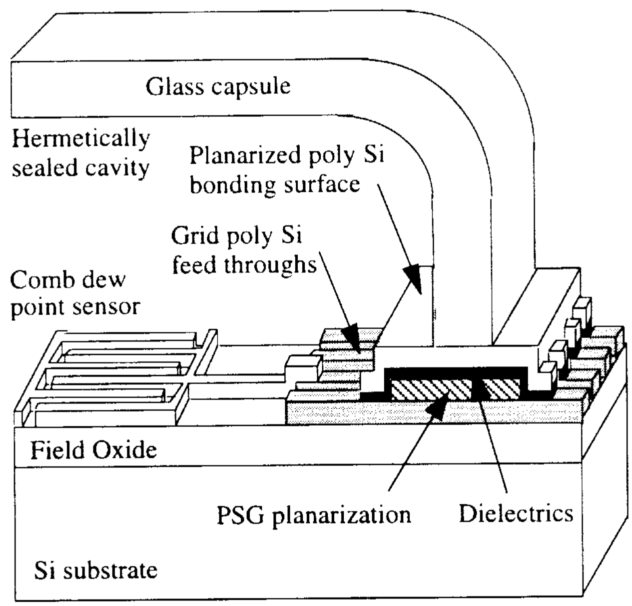


Figure 3: The structure of the hermetic package with grid feedthroughs.

During the past years we have electrostatically bonded and soak tested over one hundred and sixty of these packages. The packages successfully prevent leakage in soak tests at 95°C for over 4 months on average and at 85°C for over 17 months in deionized water. The bonding yield has varied between 85% to 72% (yield is defined as the percentage of packages which last more than 24 hours in the solution they are soaked in). It should also be mentioned that the earlier tests that have been ongoing for more than about 2 years (room temperature soak tests in saline and the 85°C and the 95°C tests in deionized water) have been made with silicon substrates that are thinned (~150μm) and bonded to the custom molded glass capsules. More recent tests (85°C and 95°C tests in saline) are performed with the silicon substrates having full thickness (~500μm) and bonded to the ultrasonically machined glass capsules with a flat top surface. We have also fabricated a low profile package with a smaller cavity by creating a recess in the glass capsule; this package could specifically be used for the encapsulation of integrated components on a circuit chip. We have performed soak tests both with deionized water and phosphate buffered saline during the past year. We currently have devices tested in deionized water for over 2.8 years at 85°C. The in-vivo test results from both the normal package and the smaller package reveal that the devices are biocompatible and rugged. Earlier tests in saline have shown that the package fails primarily because of the dissolution of polysilicon in saline at elevated temperatures. We have started new soak tests in saline during this quarter which will be discussed in a later section of this report.

2.1.1 Ongoing Accelerated Soak Tests in Deionized Water

We have continued accelerated soak testing of the package this quarter and 20% of the packages have now surpassed two and a half years of accelerated testing with no sign of moisture penetration. For these tests we have chosen temperature as the accelerating factor since it is an easy variable to control and also the diffusion of moisture is a strong (exponential) function of temperature. These tests were started by soaking 10 samples each at 85°C and 95°C. Tables 2 and 3 below list some pertinent data from these soak tests. Figure 4 summarizes the final results from the 95°C soak tests and Figure 5 summarizes the results so far from the 85°C tests. These figures also list the causes of failure for individual packages when it is known, and they show a curve fit to our lifetime data to illustrate the general trend. The curve fit, however, only approximates the actual package lifetimes since some of our packages failed due to breaking during testing rather than due to leakage.

At the beginning of this quarter, we had 4 packages soaking at 85°C. All of these 4 packages have survived to the end of this quarter and are being tested. For these packages we define failure as the room temperature condensation of moisture inside the package. The testing sequence for these packages consist of cooling the sample to room temperature from its soak bath at the elevated temperature. This is followed by a DI water rinse and nitrogen dry. We next measure the impedance of the dew point sensors and inspect the sample carefully for leakage under the microscope. The significant change in impedance (about 2 orders of magnitude) and observation of visible condensation inside the package would both be classified as the failure of the package under test. Of the original 10 samples in the 95°C tests, the longest lasting package survived for a total of 484 days. The calculated mean time to failure of these packages are 135.7 days excluding the handling errors. Of the original 10 packages in the 85°C soak tests there are still 4 with no sign of room temperature condensation. The longest lasting package in the 85°C tests has lasted a total of 1047 days and is still under test. The worst case mean time to failure for these tests has been calculated as 828.6 days excluding the handling errors. We have started a new set of soak tests as mentioned later in this report.

Table 2: Key data for 95°C soak tests in DI water.

Number of packages in this study	10
Soaking solution	DI water
Failed within 24 hours (not included in MTTF)	1
Packages lost due to mishandling	2
Longest lasting packages in this study	484 days
Packages still under test	0
Average lifetime to date (MTTF) including losses attributed to mishandling	*118.7 days*
Average lifetime to date (MTTF) not including losses attributed to mishandling	*135.7 days*

Table 3: Key data for 85°C soak tests in DI water.

Number of packages in this study	10
Soaking solution	DI water
Failed within 24 hours (not included in MTTF)	2
Packages lost due to mishandling	3
Longest lasting packages so far in this study	1047 days
Packages still under tests with no measurable room temperature condensation inside	4
Average lifetime to date (MTTF) including losses attributed to mishandling	*527.8 days*
Average lifetime to date (MTTF) not including losses attributed to mishandling	*828.6 days*

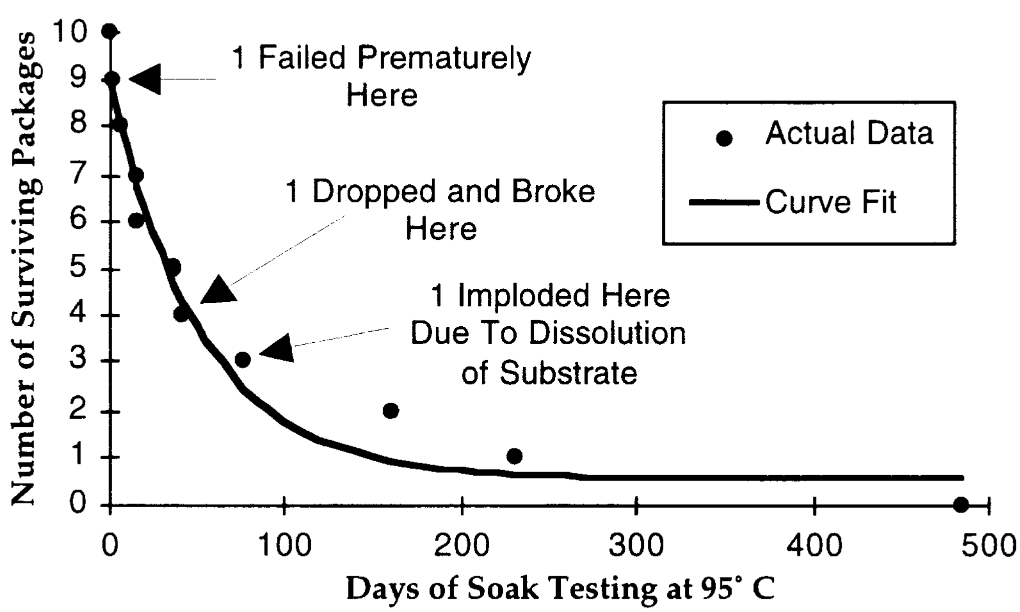


Figure 4: Summary of the lifetimes of the 10 packages which have been soak tested at 95° C in DI water.

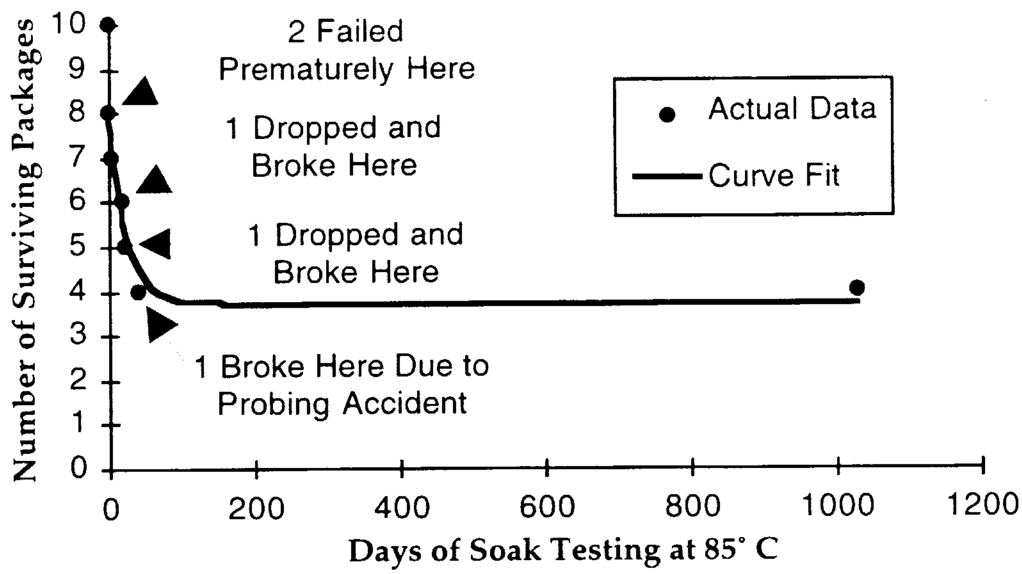


Figure 5: Summary of the lifetimes of the 10 packages which have been soak tested at 85° C in DI water.

2.1.2 Interpretation of the Long Term Soak Test Results in Deionized Water

Generally during accelerated testing, one models the mean time to failure (MTTF) as an Arrhenius processes (In the VLSI industry this model is used for failure due to diffusion, corrosion, mechanical stress, electromigration, contact failure, dielectric breakdown, and mobile ion/surface inversion). The generalized equation used in all these cases is given below where MTTF is the mean time to failure, A is a constant, ξ is the stress factor other than temperature, (such as pressure or relative humidity), n is the stress dependence, Q is the activation energy, K_B is Boltzman's constant, and T is the temperature in Kelvin.

$$MTTF = A \cdot \xi^{-n} \cdot e^{\left(\frac{Q}{K_B T}\right)}$$

For the accelerated soak tests that we have performed on the packages, there was no stressing factor other than temperature, so the ξ term drops out of the above equation. The resulting equation can be rewritten as a ratio of MTTFs as it is below. This is the model we are using to interpret the accelerated soak tests performed during the past year.

$$AF = \frac{MTTF_{Normal}}{MTTF_{Accelerated}} = e^{\frac{Q}{K_B}\left(\frac{1}{T_{Normal}} - \frac{1}{T_{Accelerated}}\right)}$$

By using these MTTFs at 85°C and 95°C, we can easily calculate the activation energy (Q) and from this activation energy we can proceed to obtain an acceleration factor (AF) for these tests, and then calculate the MTTF at the body temperature. Moreover, after analyzing our failed samples we have found out and mentioned in the past progress reports that some of the samples at the 95°C tests have failed prematurely due to the enhanced dissolution rate for silicon at this temperature. Since the dissolution reaction is an exponential function of temperature, the samples at the 85°C tests have been effected less than the ones at 95°C. The model we use only accounts for acceleration of moisture diffusion, but not dissolution. We will still keep and update the data for the tests performed at 85°C. Moreover, for our calculations we assume that all the samples in the 85°C tests have also failed the same time as the longest going sample in the 95°C tests and proceed with the calculations as follows:

$$MTTF\big|_{85^\circ C} = 257.6\,Days \quad MTTF\big|_{95^\circ C} = 118.7\,Days$$

Q=0.88 eV, AF(95°C)=179.5, AF(85°C)=82.7

$$MTTF\big|_{37^\circ C} = 58.4\,Years$$

We should also note that we have included every single sample in the 85°C and 95°C soak tests in this calculation except the 15% which failed during the first day (we assume that these early failures can be screened for). Moreover, some of these capsules have failed due to mishandling during testing rather than due to actual leakage into the package. If we disregard the samples that we have attributed failure due to mishandling we obtain a longer mean time to failure:

$$MTTF\big|_{85^\circ C} = 396\,Days \quad MTTF\big|_{95^\circ C} = 136\,Days$$

Q=1.217 eV, AF(95°C)=1304, AF(85°C)=447

$$MTTF\big|_{37^\circ C} = 485\,Years$$

It should be noted that these values should be considered cautiously because these calculations are made with no ongoing tests at 95°C (since these samples prematurely failed). These calculations only show that any way the MTTF is estimated, a very long lifetime is expected of these packages in aqueous environments..

2.1.3 New Accelerated Soak Tests in Saline

We have prepared a group of glass-silicon packages with the ultrasonically machined glass capsules and the microstimulator substrates during this quarter. The packages have been coated with silicone rubber and cured at room temperature for 24 hours. A sample device is shown in Figure 6 below. We have just started soaking a set of 5 devices each at 85°C and 95°C. So far, we do not have sufficient results from these tests, but we will update them as they become available in the next progress report.

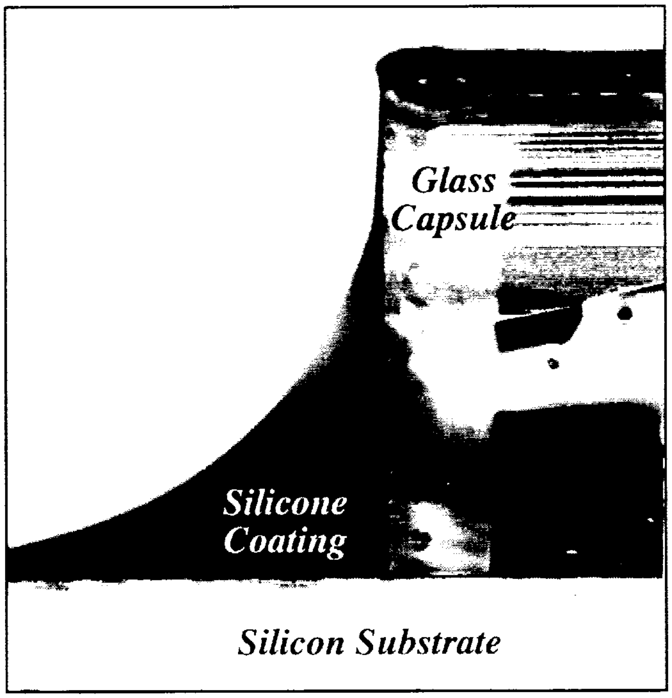


Figure 6: The photograph of a silicone-coated glass-silicon package.

2.1.4 Ongoing Room Temperature Soak Tests in Saline

During the past two and a half years we have been soaking a group of packages in phosphate buffered saline at room temperature in order to obtain test data independent of the acceleration technique used. Admittedly, the room temperature tests will take a long time to produce meaningful data, however, the results obtained this way will act as a good control study to verify the overall integrity of our package.

We have soaked 6 packages in saline at room temperature. One of these packages failed within one day, most likely due to surface defects or poor bonding due to misalignment. Another one failed after 160 days of soaking. The remaining 4 samples are dry and still under test. These samples, similar to our other samples, are tested visually with the aid of a microscope and electrically with the help of dew point sensors integrated into the package substrate. The longest lasting sample in these tests has reached a total of 939 days and is still under test. We have calculated a worst case mean time to failure of 776 days for these samples.

2.1.5 Dissolution Experiments

As has been discussed in this and previous reports, one of the main problems that we have faced in conducting long-term accelerated tests in saline environments is that the polysilicon layer used for bonding glass to the silicon substrate is dissolved away in saline at these elevated temperatures. This quarter we have initiated some tests to obtain a quantitative measure of how fast this dissolution occurs. To do this, a number a test devices have been prepared. A set of silicon wafers have been oxidized and coated with a layer of LPCVD polysilicon of about 1µm in thickness. The polysilicon is then patterned using RIE and its thickness is measured using a profilometer. The devices were soaked in DI water and in saline at 85°C and 95°C for periods of 12 hours and 24 hours. Table 5 summarizes the results from these tests. The step heights were later measured and from the difference a dissolution rate was estimated. To confirm the presence of the polysilicon lines, we have measured their resistance and found them within acceptable range. For the case where the entire polysilicon layer was gone, we have measured a very high resistance as expected since the layer below the polysilicon is the oxide layer. The dissolution of the silicon dioxide was considered negligible compared to the polysilicon. This assumption was later verified with the use of a SEM which showed the oxide layer having the same thickness both before and after the soak test. This data clearly shows that the polysilicon layer is attacked much faster in saline than in DI water, and that the dissolution rate is fast enough to limit the lifetime of the tests carried out at 95°C. In previous reports we had presented data indicating that when the polysilicon is coated with silicone rubber the MTTF at elevated temperatures indeed improves drastically. We will continue to conduct additional tests on determining the dissolution rates of various thin films in saline at body temperature to determine if these films will dissolve after several decades of exposure to body fluids.

Table 4: Data for room temperature soak tests in saline.

Number of packages in this study	6
Soaking solution	Saline
Failed within 24 hours (not included in MTTF)	1
Packages lost due to mishandling	1
Longest lasting packages in this study	939 days
Packages still under tests with no measurable room temperature condensation inside	4
Average lifetime to date (MTTF)	*776 days*

Table 5: The dissolution rates of polysilicon in saline and DI water.

Solution/Temp.	85°C	95°C
Saline	0.6µm/day	1.6µm/day
DI water	0.05µm/day	0.15µm/day

2.3 Packaging and Microtelemetry For Next Generation Microstimulators

The single-channel microstimulator that has been under development for the past few years, is about 3 orders of magnitude smaller than conventional implantable stimulation units that use hybrid thin-film technology. As part of our contract goals, we are developing miniature packages for a variety of implantable neural prostheses. In order to minimize the size of these packages, we have been examining ways to reduce the volume of implantable stimulators by another order of magnitude. Figure 7 illustrates how this size reduction can be achieved. By far the largest components in the microstimulator system are the charge storage capacitor and the discrete receiver coil. These two components take up about 90% of the total microstimulator volume. As shown in Fig. 7, the volume of the microstimulator can be reduced by an order of magnitude by integrating the receiver coil directly on the CMOS substrate and by not using a charge storage capacitor. While the microstimulator is currently about 2.5 mm thick and has a volume of about 50 mm^3, a system with an integrated coil and no charge storage capacitor will be in the 300μm to 500μm thickness range and have a volume of about 6 mm^3. We call these extremely low volume FES systems mini-microstimulators.

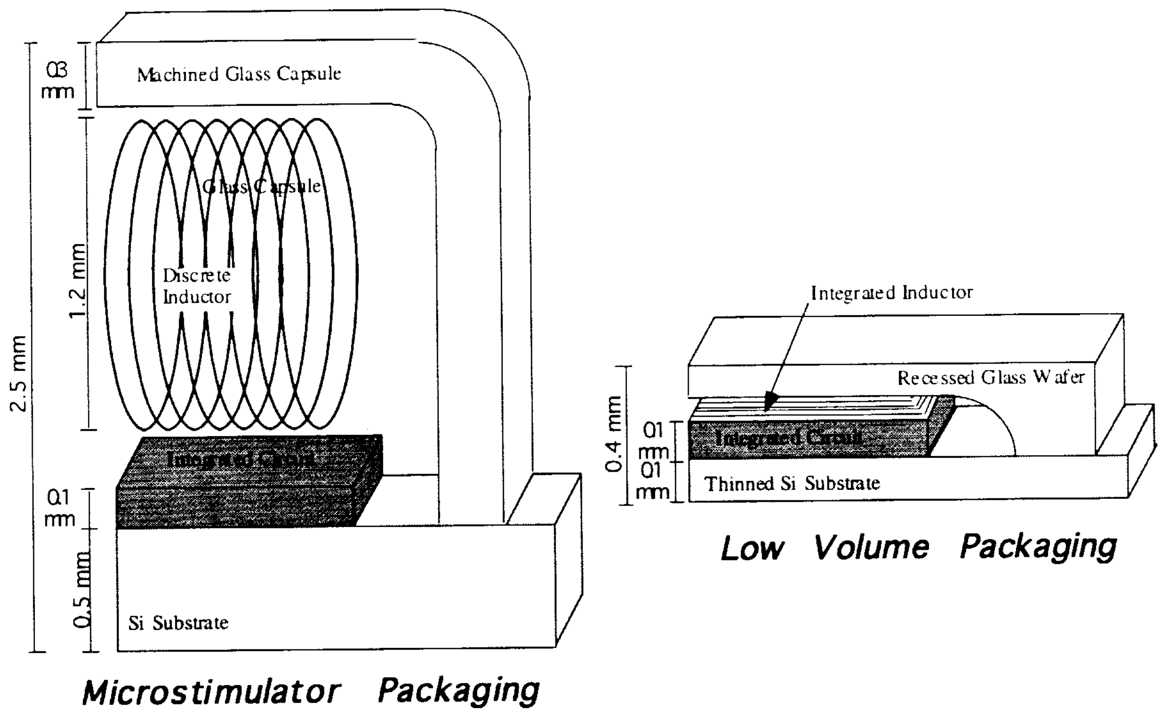


Figure 7: A scale drawing comparing the volume of the microstimulator with the volume of a mini-microstimulator.

Figure 8 shows one of the integrated receiver coils that we have developed for use in mini-microstimulator systems. This coil has 14 turns, dimensions of 2 mm by 10 mm, and has electroplated copper windings and an electroplated nickel-iron (NiFe) core. The coil in Figure 8 has integrated RF receiver circuitry mounted on top of it for telemetry testing. This circuitry includes a 4 MHz tuned RF receiver, a supply voltage generator, a clock recovery circuit, and a data demodulator. The coils and RF receiver circuit have been successfully tested telemetrically, and over 20 mW of power was received at a distance of 3cm from the transmitter. Although the circuitry and the coil in Figure 8 are on separate silicon substrates which have been hybrid attached, the coil technology is fully CMOS compatible, and in the future they will be fabricated together.

We are developing a nerve cuff stimulation system to demonstrate the feasibility of a telemetry powered mini-microstimulator. Stimulating nerve cuffs are a well suited application for a mini-microstimulation device because they need relatively low current levels. Typical nerve cuff stimulation levels are 100 μA to 2 mA, which is a good fit with the 3 mA output that is feasible using on-chip coils and no charge storage capacitor (for comparison the microstimulator stimulates with an output current of 10 mA or more). Table 6 summarizes the specifications for the full 8 channel nerve cuff system which we are developing, and Figure 9 shows an exploded view of such a system. Note that the nerve cuff and electrodes can be either integrated directly with the hermetic packaging substrate, or the nerve cuff could be attached by a connector.

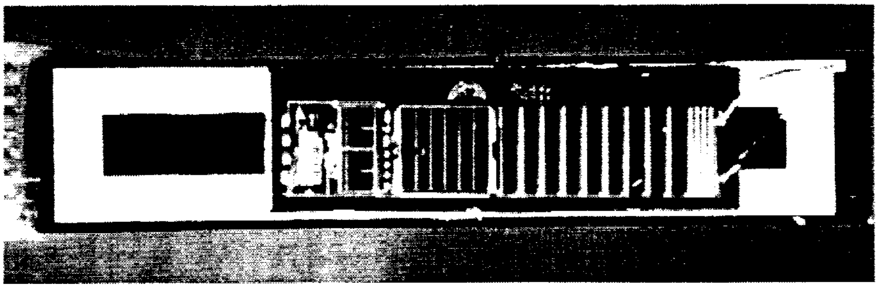


Figure 8: Photograph of the integrated RF receiver circuitry mounted on top of a 2 by 10 mm, 14-turn on-chip. This 1.29 by 5.78 mm circuit includes a 4 volt generator, a data demodulator, and a clock recovery circuit.

Table 6: The specifications for a telemetry powered stimulating nerve cuff.

8-Channel Peripheral Nerve Stimulation System Specifications	
General	
Dimensions = 2.0 mm X 10 mm X 0.5 mm	Power Delivery = Telemetry
Power Consumption < 15 mW	On Chip Regulated Supply = 4 Volts, Gnd
Telemetry Link	
Receiver Coil = On-chip (2.2 mm X 10 mm)	Range = 3 cm
Transmitter Coil = Planar, air core (80 mm dia.)	Carrier Frequency = 4 MHz
Modulation Frequency = 1 kHz to 50 kHz	
Stimulation	
Output Channels = 8	Amplitude = 0 to 2 mA (62.5 µA steps)
Duration = 0 to 2047 µS (2 µS steps)	Stimulation Protocol = Bi-phasic
Frequency ≤ 50 Hz	Output Load < 1.5 KΩ

This quarter we have layed out the RF receiver circuitry and the digital control circuitry for the complete eight channel nerve cuff stimulation system. We will layout the stimulating output circuitry and fabricate the complete system during the coming quarter.

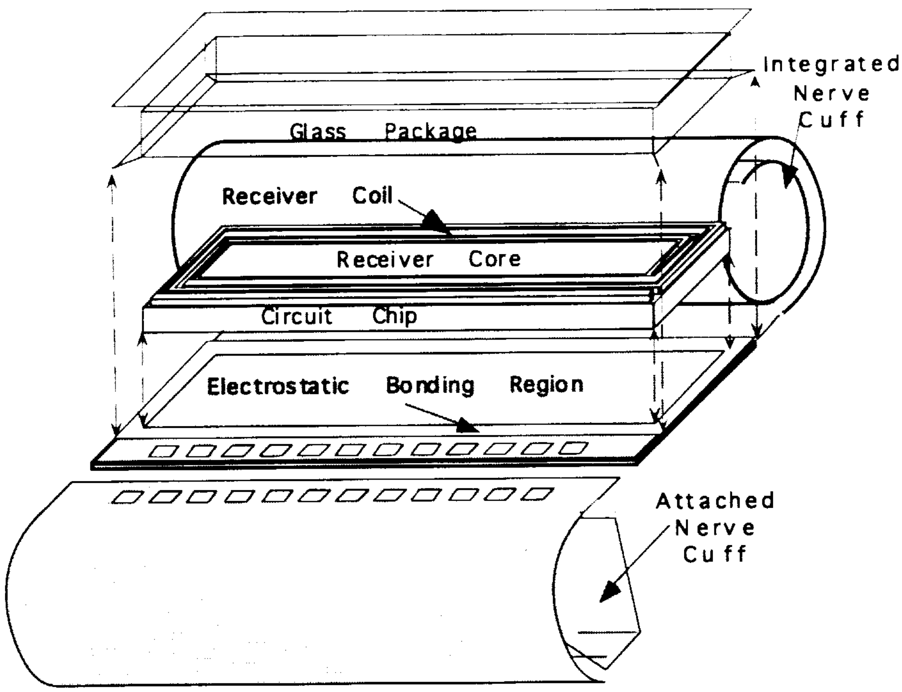


Figure 9: One mini-microstimulator application is this nerve cuff. The nerve cuff can be either integrated directly with the packaging substrate, or attached by a connector.

2.3.1 Layout of the Mini-Microstimulator Digital Control Circuitry

The circuitry for the 8-channel nerve cuff stimulation system has been designed, simulated and discussed in our previous quarter report. This quarter the large digital control circuitry was physically layed out. A block diagram of the digital circuitry is shown in Figure 10. This circuitry interprets and stores the data that is received telemetrically, it checks the data for proper parity and address bits, and it controls the electrode selection, the timing, the magnitude and the phase of the output stimulation waveform. The digital circuitry contains 2,300 transistors, and a printout of the layout is shown in Figure 11. This circuitry is 2 mm wide by 3.5 mm long, and it dissipates no static power as it is entirely CMOS.

The analog front end circuit blocks for this system (including the RF receiver, the supply voltage generator, the data demodulator, and the system clock) have also been layed out. This analog front end circuitry was fabricated last year for testing the on-chip coils, and it is shown in Figure 8. Now that the digital circuit block is layed out, all that remains before fabrication can begin is the layout of the stimulation output circuit block (including the programmable amplitude output current source, and the output de-multiplexers). We plan to complete the layout of the stimulation output circuit block in the next few weeks.

2.3.3 On-Chip Receiver Coils

We have continued testing and evaluating the on chip coils this quarter. Figure 12 shows a photograph of the testing setup for telemetry testing the coils. A micromanipulator allows the on-chip receiver coil to be precisely positioned with respect to the transmitter coil. As can be seen in Figure 12, we use a planar, spiral transmitter coil, and a battery powered class E transmitter for these tests.

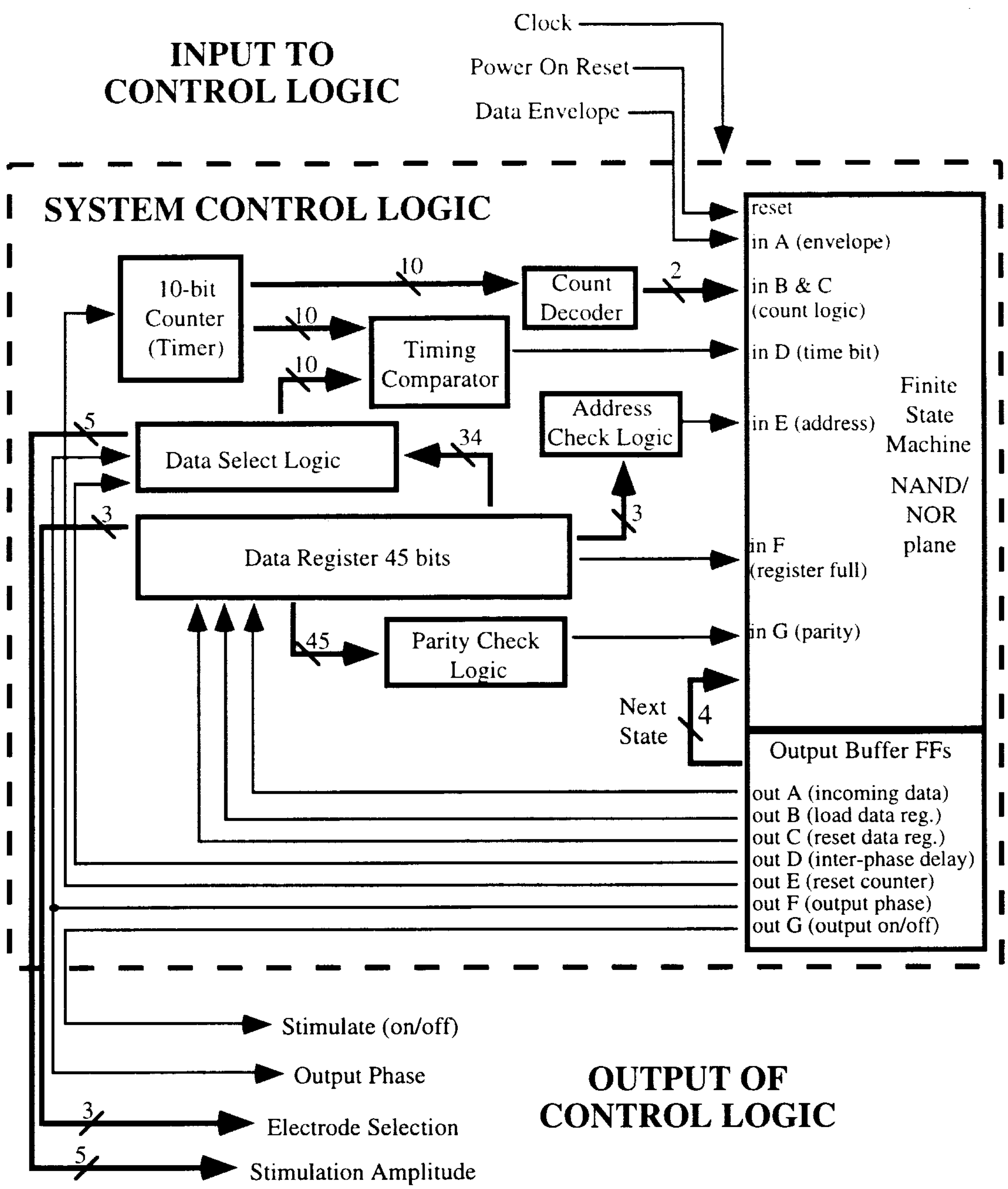


Figure 10: Block diagram of the nerve cuff stimulation system logic circuitry.

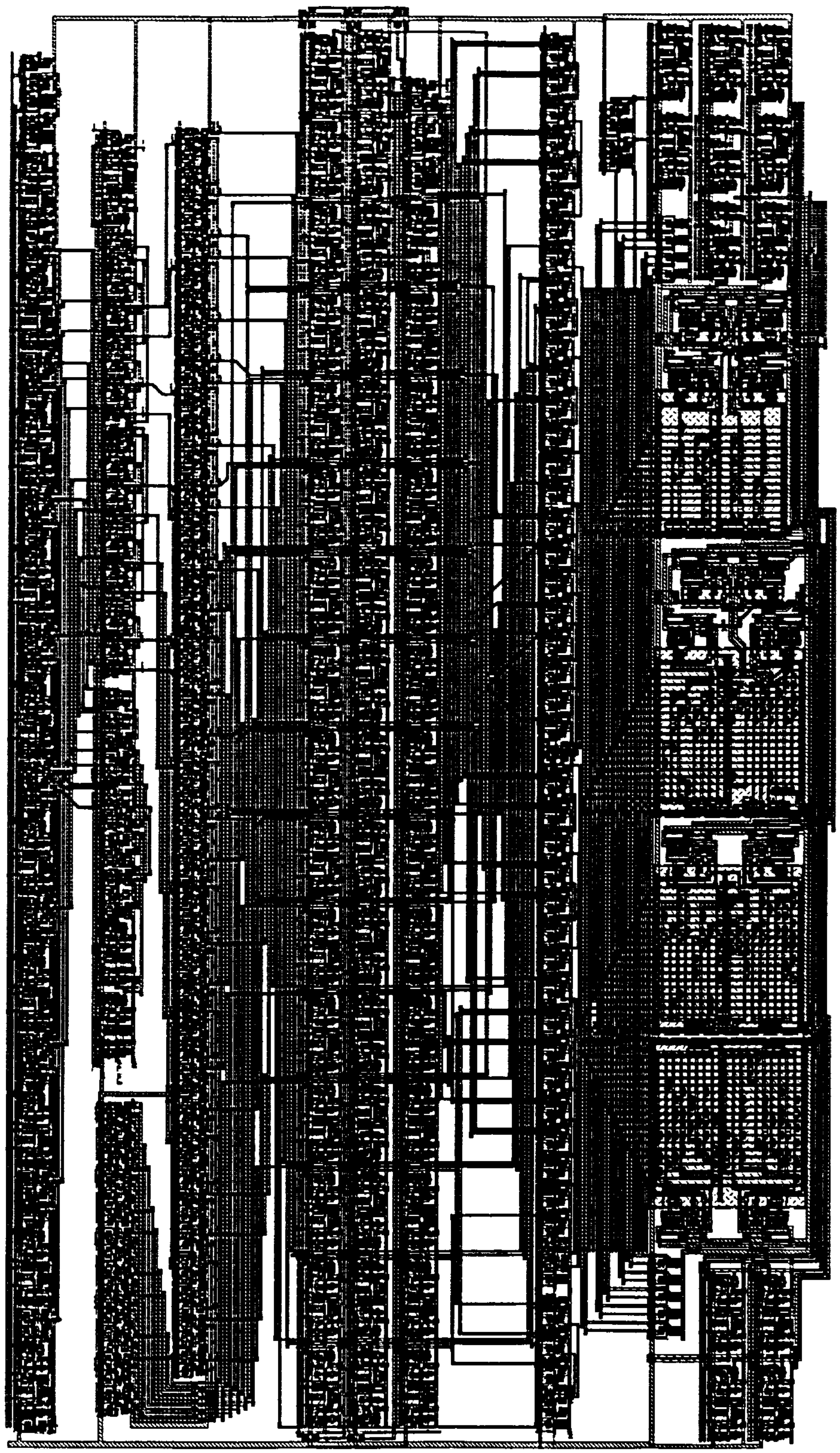


Figure 11: The layout of the nerve cuff stimulation system logic.

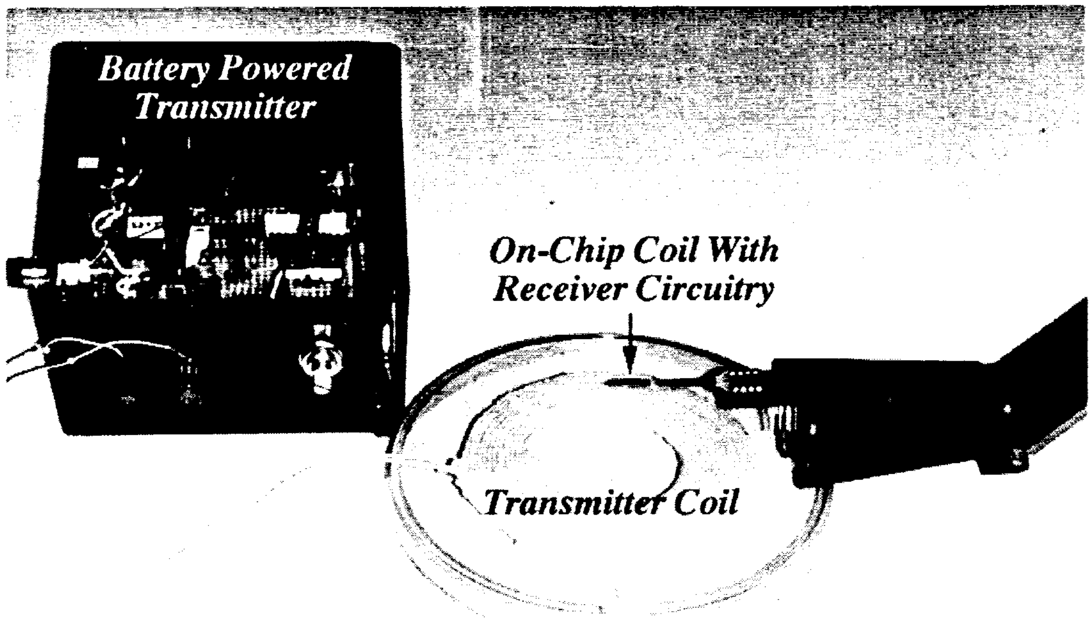


Figure 12: The telemetry testing setup.

This quarter measurements were made of the power received as a function of the axial misalignment of the coils. It is important to quantify how the received power falls off with axial coil misalignment, because in actual use it will be difficult to perfectly align the coils. Figure 13 shows measured results of received power as a function of axial misalignment of the coils. For these measurements, a 2 by 10 mm air-core, on-chip receiver coil and a 3.8 cm average diameter transmitter coil were used. As can be seen in the figure, the power received actually increases with coil misalignment until the receiver is misaligned by about half of the radius of the transmitter (about 2 cm in this case). This effect is described in [1]. The received power falls off quickly if the coils are misaligned by more than half the radius of the transmitter. Up until now, all of the result that we have reported were for co-axial transmitter and receiver coils. Figure 13 shows that these were not best case measurements, but that rather there is a wide range of misalignment which can be tolerated with even higher coupling. The measurements shown in Figure 13 were obtained with air core coils, but NiFe core coils yield a similar shaped curve.

In the coming quarter we will complete layout of the nerve cuff mini-microstimulator circuitry (Although the analog receiver part of this circuit and the digital control part of this circuit have been laid out, layout on the stimulating output circuitry still needs to be completed). We will also include the latest version of the single channel microstimulator circuitry and the multi-channel microstimulator circuitry on this mask set. Fabrication will begin as soon as the layout is complete, and we plan to have our first test results from this circuitry by early fall.

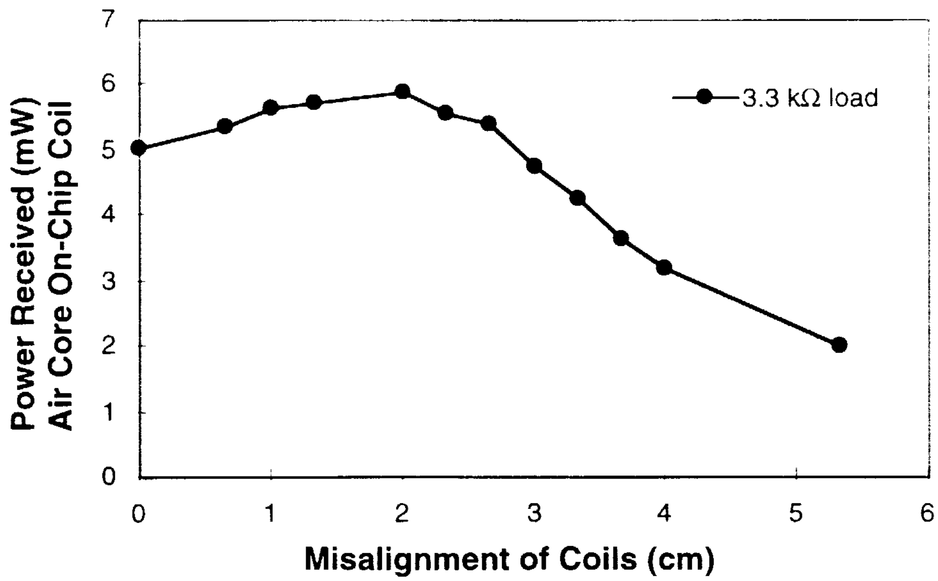


Figure 13: Received power as a function of the axial misalignment of coils. The planar transmitter coil used for this measurement has an average winding radius of 3.8 cm.

3. ACTIVITIES PLANNED FOR THE COMING QUARTER

Our efforts on the various aspects of this project will continue in the coming quarter. First, we will continue soak tests of glass-silicon packages in saline and will acquire additional soak test data to complement that we obtained previously. We will continue to measure the dissolution rate of various thin films in saline solutions and will develop techniques for preventing this dissolution at higher temperatures so that long-term accelerated tests could continue to be conducted.

In the area of microstimulator development we will complete the fabrication of another run of wafers that contain both the design for the single-channel microstimulator and the multichannel stimulator for a peripheral nerve stimulation system. The layout for both of these is almost complete and will go out for masks. We expect to have complete tests results available for all of these circuits by the end of the next quarter.

Finally, we will continue to work with a number of groups that have been interested both in microstimulators and in our packaging technology, including Vanderbilt University, VA Hines Hospital, and Case Western Reserve University. Results from these collaborations will be reported as they become available.

REFERENCES

[1] F.C. Flack, E.D. James, D.M. Schlapp, "Mutual Inductance of Air-cored Coils: Effects on Design of Radio-Frequency Coupled Implants", *Med. & Biol. Eng.* Vol. 9, pp. 79-85, 1971